



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/265,307	03/09/1999	NIGEL L. WEBB	N0260/7031(E)	4390

7590 08/11/2006

EDWARD R GATES
WOLF GREENFIELD AND SACKS
600 ATLANTIC AVENUE
BOSTON, MA 02210

EXAMINER

RAHMANI, NILOOFAR

ART UNIT	PAPER NUMBER
----------	--------------

1625

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/265,307

Applicant(s)

WEBB ET AL.

Examiner

Niloofer Rahmani

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 1999.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>06/15/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are

1,5,7,12,17,21,23,28,33,57,62,65,69,70,75,78,82,84,89,90,94,97,101,103,107,108,110,114 and 119-201.

Continuation of Disposition of Claims: Claims rejected are

1,5,7,12,17,21,23,28,33,57,62,65,69,70,75,78,82,84,89,90,94,97,101,103,107,108,110,114 and 119-201.

DETAILED ACTION

1. Claims 1, 5, 7, 12, 17, 21, 23, 28, 33, 57, 62, 65, 69-70, 75, 78, 82, 84, 89-90, 94, 97, 101, 103, 107-108, 110, 114, 119-201 are currently pending in the instant application. Claims 2-4, 6, 8-11, 13-16, 18-20, 22, 24-27, 29-32, 34-56, 58-61, 63-64, 66-68, 71-74, 76-77, 79-81, 83, 85-88, 91-93, 95-96, 98-100, 102, 104-106, 109, 11-113, 115-118 are cancelled.

2. ***Response to Amendment***

The Declaration under 37 CFR 1.132 filed on 07/20/2004 is insufficient to overcome the rejection of claims 1, 5, 7, 12, 17, 21, 23, 28, 33, 57, 62, 65, 69, 70, 75, 78, 82, 84, 89, 90, 94, 97, 101, 103, 107, 108, 110, 114, 119-201 based upon 35 U.S.C. 103(a) as set forth in the last Office action because: No weight is given to an opinion on the ultimate legal conclusion in issue. See *In re Lindall*, 155 USPQ 521; *In re Chilowsky*, 134 USPQ 515.

3. ***Claim Rejections - 35 USC § 103***

The rejection of claims 1, 5, 7, 12, 17, 21, 23, 28, 33, 57, 62, 65, 69, 70, 75, 78, 82, 84, 89, 90, 94, 97, 101, 103, 107, 108, 110, 114, 119-201 over Yoshida et al., Kataoka et al., Rentsch et al. under 35 U.S.C. 103(a) is maintained for reason of record. Applicants argue that as pointed out in the Declaration by Dr. Balthasar, the Examiner's conclusion is contradicted by other scientific literature, as well. Dr. Balthasar provided examples from the literature that demonstrated that slow release of anti-cancer drugs, where the time-course

Art Unit: 1625

of drug circulation is prolonged, can actually decrease MTD. It is the examiner's position that the Dr. Balthasar Declaration is Opinion Declaration.

4. Double Patenting

The rejection of claims 1, 5, 7, 12, 17, 21, 23, 28, 33, 57, 62, 65, 69, 70, 75, 78, 82, 84, 89, 90, 94, 97, 101, 103, 107, 108, 110, 114, 119-201 over claim 7 of US 6,602,902 under Obvious Double Patenting is maintained for reason of record. Applicants argue that the test for Obviousness-type double patenting is whether the pending claims would have been obvious over issued claim 7. The test is not whether the pending claims would infringe or be "embraced by" the issued claim. It is the examiner's position that the prior art claim is species of the instant claims. On column 5, lines 19-25 of '902 the pharmaceutical agent is an anti-cancer agent included specifically taxanes e.g., Taxol and Taxotere. On columns 7-8, Example 1, conjugate 1 and on columns 9-10, Example 2, conjugate 2 are some examples of covalent conjugate of cis-docosahexanoic acid and a noncentral nervous system active agent. Since the prior art does not mention the MTD, then it is inherently there.

5. Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory

Art Unit: 1625

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

08/07 /2006

NR


THOMAS MCKENZIE

SPE

GROUP 1625